ANNEX 3

INTERACTION BETWEEN THE NANOTECHNOLOGY CHARACTERIZATION LABORATORY AND NANOTECHNOLOGY PROVIDERS (NCL MATERIAL TRANSFER AGREEMENT ADDENDUM 1)

[Note: This annex is for reference purposes only. It will apply only to providers whose nanotechnology strategies have been selected for characterization by the NCL.]

This document describes the agreement between the Nanotechnology Characterization Laboratory (NCL) at the National Cancer Institute at Frederick (NCI-Frederick) and provider's name here located in city/state to characterize name of nanoparticle or nanostrategy. It is an amendment to the NCL Business Plan and Material Transfer Agreement and is intended to supplement information provided in those documents.

Your nanotechnology particle/material/device/strategy has been selected for characterization by the NCL because it has the potential to impact cancer therapeutics or diagnostics.

The NCL will characterize your technology by subjecting it to a panel of assays to determine its efficacy, safety, and potential for human use in clinical cancer trials. Those assays will analyze the technology's physical characteristics, in vitro properties, and in vivo behavior in animal models. The assay cascade is anticipated to take at least 12 months. You can expect to be invited to at least two data reviews during NCL's characterization.

Characterization by the NCL is a government-provided service; there are no fees or charges.

Physical samples of your technology will be submitted to the National Institute of Standards and Technology (NIST) for characterization, as described in the NCL Business Plan.

All materials must be transported/shipped to the NCL in accordance with all applicable laws, regulations, and environmental, health, and safety provisions.

Data gleaned from the NCL assay cascade are intended to be included in an investigator-led filing of an Investigational New Drug (IND) with the FDA. These data by themselves will not be sufficient to meet FDA's requirements for an IND. If NCL's assays predict favorable in vivo safety and efficacy, NCI and NCL anticipate your organization will want to pursue the translation of your technology into clinical applications.

The NCL assumes that you have acquired and secured your intellectual property (IP) prior to submitting your nanotechnology to the NCL for characterization. Given the "multifunctional" nature of nanotechnology platforms, your technology may be one component in a larger system that is used in clinical research. As an example, scientists at the NCL may chemically "tag" your nanoparticles/material with compounds (e.g., gadolinium) that aid in monitoring/tracking its in vivo efficacy.

Information and data related to your nanotechnology strategy will be presented to NCL's Technical Steering Committee, to aid in the evaluation of your technology.

The NCL reserves the right to cease characterizing your technology if that option is determined to be in the best interests of NCI.

The NCL is a national resource intended to advance nanotechnology research and development related to cancer therapy and diagnostics. Once characterized, the data generated from your material may be presented in scientific and public forums if such data are deemed to benefit the cancer research community. The NCL may wait up to 90 days after data are provided to you before disclosing them in a public forum. This public disclosure pertains only to data generated at the NCL; your company's proprietary/confidential information will be protected by the NCL in accordance with the Material Transfer Agreement.

For NCI:

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Date Authorized Signature for NCI and Title

NCI's Official and Mailing Address for correspondence related to this agreement:

Technology Transfer Branch
National Cancer Institute
Fairview Center, Suite 500
1003 West 7th Street
Frederick, MD 21702

For Provider:

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Date Provider's Investigator and Title

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Date Authorized Signature for Provider and Title

Provider's Official and Mailing Address: